

Amendments to the Claims:

In accordance with 37 CFR § 1,121, please amend the above-identified application as set forth below.

1. (Original, now cancelled) A continent ostomy port device comprising:
 - (a) a generally planar face plate defining a selectively sealable aperture which is formed through and is alignable with the opening of a stoma formed in the body of a user of the device when the generally planar face plate of the device is disposed substantially parallel to the body wall of the user, over the site of the stoma, to thereby provide access to the inside of the stoma;
 - (b) a closure portion connected to the generally planar face plate adjacent to the aperture and adapted to permit selective and repeatable covering and uncovering of the aperture in the generally planar face plate; and
 - (c) a catheter portion having a first end and a second end, the first end of the catheter portion being connected to and extending from a side of the face plate which is disposed proximally when the port device is in normal use position, the catheter portion extending proximally and the second end of the catheter portion being disposed interior of the user's body, within the ostomy site when the port device is in normal use, the catheter portion having a continuous and generally cylindrical exterior side wall, and a continuous, generally cylindrical interior side wall defining a major lumen, the major lumen extending continuously from the aperture in the generally planar face plate to the second end of the catheter portion, the catheter portion being sized and shaped appropriately for non-surgical insertion through a stoma to a sufficient distance that the presence of the catheter portion within the stoma provides a physical

barrier which reduces prolapse without the use of extraneous, externally applied materials or additional surgery.

2. (Original, now cancelled) The device of Claim 1, and further comprising a removable cartridge sized and shaped to fit snugly and slideably within the major lumen of the catheter portion of the device so as to be liquid-tight and to thereby prevent inadvertent escape of body waste material from the stoma through the device when the cartridge is in place, so that the user is not required to wear an ostomy bag, and to further thereby clean the interior side wall of the catheter portion as the cartridge is pressed into the major lumen of the catheter.

3. (Original, now cancelled) The device of Claim 2, wherein the cartridge is formed of a material which is permeable to gasses but impermeable to solid and liquid waste, the cartridge further being provided with an odor control substance to thereby reduce the natural odor of any gasses that escape from the stoma site through the cartridge in the port device.

4. (Original, now cancelled) The device of Claim 3, wherein the odor-control substance is selected from the group consisting of charcoal, zinc and sodium bicarbonate.

5. (Original, now cancelled) The device of Claim 3, wherein the closure is provided with a vent opening to thereby permit the gradual escape of gasses which pass through the cartridge in the catheter portion even when the closure portion is in a closed position, substantially entirely covering the aperture in the generally planar face plate and thereby ensuring that the cartridge portion does not become inadvertently dislodged.

6. (Original, now cancelled) The device of Claim 1, and further comprising a selectively operable anti-reflux valve attached at the second end of the catheter portion, to thereby permit blockage of the major lumen by activation of the anti-reflux valve when it is desired to prevent

escape of body waste through the port device, and to permit passage of fluid or solid material through the major lumen of the port device when the anti-reflux valve is deactivated.

7. (Original, now cancelled) The device of Claim 1, and further comprising retaining structure connected to the catheter, the retaining structure being non-surgically, snugly fittable into the stoma, to cause the port device to be self-retaining in a normal use position within a stoma of the user, without the need for special surgery and extraneous, external fixation materials such as tape, belts, and adhesives.

8. (Original, now cancelled) The device of Claim 7, wherein the retaining structure is a bolster formed around at least a portion of the exterior side wall of the catheter, the bolster being formed to provide a secure but comfortable seal internally of the body of the user, proximal to the stoma site at which the device is implanted.

9. (Original, now cancelled) The device of Claim 7, and further wherein the retaining structure is bioresponsive, to thereby permit the port device to be indwelling for extended periods of time, at least in the order of days, without causing tissue irritation or damage around the stoma.

10. (Original, now cancelled) The device of Claim 8, wherein the bolster is formed of a foam material which expands upon insertion into the body of the user of the device.

11. (Original, now cancelled) The device of Claim 10, wherein the foam of which the bolster is formed is closed-cell polyurethane foam.

12. (Original, now cancelled) The device of Claim 8, wherein the bolster is formed at least one annular hemispherical ridge disposed co-axially on the exterior side wall of the catheter portion spacedly from the proximally disposed surface of the face plate.

13. (Original, now cancelled) The device of Claim 8, wherein the bolster is formed in a cone shape and disposed coaxially on the exterior side wall of the catheter, with the small end of the cone shape disposed distally and the large end of the cone disposed proximally when the port device is in normal use position.

14. (Original, now cancelled) The device of Claim 8, wherein the bolster is formed as at least one arcuate ridge disposed entirely around the exterior side wall of the catheter proximally and spacedly from the proximally disposed surface of the face plate.

15. (Original, now cancelled) The device of Claim 8, wherein the bolster is formed as a bell-shape disposed co-axially around the catheter with the large end of the bell disposed on the end of the catheter which is proximal in use and the small end of the bell spaced proximally from the proximal side of the face plate.

16. (Original, now cancelled) The device of Claim 8, wherein the bolster comprises elongated flexible members, the elongated flexible members being disposed longitudinally and circumferentially spaced apart around the exterior side wall of the catheter, and being connected at opposed ends of each of the flexible members to the exterior side wall of the catheter, the elongated flexible members being capable of being twisted from an original uncompressed state for insertion into the stoma, followed by immediate and automatic return to the original uncompressed state when circumferential force, which is applied for insertion of the port device into the stoma, is removed.

17. (Original, now cancelled) The device of Claim 16, wherein the elongated flexible members of the bolster are formed of metal.

18. (Original, now cancelled) The device of Claim 17, wherein the metal of which the elongated flexible members are formed is a nickel-titanium alloy generally known as nitinol.

19. (Original, now cancelled) The device of Claim 8, wherein the bolster is formed of a plurality of elongated flexible members each having a first end and a second end, the first ends of the flexible members being fixed to the proximal end of the catheter in circumferentially spaced relation to one another, and a ring member connected to the second ends of the flexible members, the second ends of the flexible members being circumferentially spaced apart around the ring member and the elongated flexible members each being foldable upon themselves so as to be obturatable to permit non-surgical insertion of the port device into a stoma of the user, and the elongated flexible members being capable of automatically returning to the normal folded state thereof after being obturated, the flexible members in the folded state having a greater diameter than in the obturated unfolded state so that the folded elongated flexible members press outwardly from the ring member against an inside wall of tissue of which the stoma is formed.

20. (Original, now cancelled) The device of Claim 6, wherein the anti-reflux valve is a balloon disposed internally of and at a proximally directed end of the catheter portion, and wherein the catheter portion of the device defines a first, narrow lumen connected to the balloon and in fluid communication with the exterior of the device for permitting selective filling and emptying of the balloon.

21. (Original, now cancelled) The device of Claim 20, and further comprising access structure disposed at the distal end of the first, narrow lumen, which access structure is suitable for repeated engagement to and disengagement from a syringe, to thereby permit selective introduction of fluid via the first narrow, lumen to inflate the balloon to block the central lumen of the catheter portion, or to remove fluid via the duct to deflate the balloon thereby permitting elimination of body wastes through the stoma via the device, as well as permitting introduction of liquid via the device to irrigate the tissue of which the stoma is formed.

22. (Original, now cancelled) The device of Claim 1, wherein the portion of the generally planar body portion is adapted in the area of the defined aperture for attachment of a hose nozzle, to thereby permit the user to selectively attach a hose for purposes of irrigation, drainage and treatment.

23. (Original, now cancelled) The combination of the device of Claim 1, wherein the device has a connector suitable for attachment of a waste collection bag to the device, and a waste collection bag having a connection spout sized for liquid-tight mating of the connector of the device to the connection spout of the collection bag, to thereby permit short-term selective collection of the user's body waste into the bag for ready disposal thereof.

24. (Original, now cancelled) The combination of Claim 23, wherein the waste collection bag is formed so as to have a low profile and to lie substantially flat against the user's body, to thereby permit the user to wear fitted clothing without the presence of the bag being readily apparent.

25. (Original, now cancelled) The device of Claim 2, wherein the cartridge comprises a tampon portion formed of material that has impregnated with the odor control substance.

26. (Original, now cancelled) The device of Claim 2, wherein the cartridge comprises a tampon portion having a central longitudinal core including the odor control substance.

27. (Original, now cancelled) The device of Claim 2, wherein the cartridge comprises a tampon portion and an end piece connected to a distally disposed end of the cartridge, the end piece having a gripping member connected thereto for facilitating handling of the cartridge and selective removal of the cartridge from the major lumen of the catheter portion.

28. (Original, now cancelled) The device of Claim 26, wherein the odor control substance is provided in the form of a tablet which is suitably sized and shaped to permit placement of the tablet between the tampon portion and the end piece.

29. (Original, now cancelled) The device of Claim 26, wherein the end piece is formed as a cap connected over the distal end of the tampon portion.

30. (Original, now cancelled) The device of Claim 1, wherein the closure portion comprises a collar connected to the disposed surface of the generally planar face plate around the selectively sealable aperture defined by the face plate, at least one detent bar fixed internally of the collar, and a cap having a shape and outside perimeter of sufficient size to permit a liquid-tight, press fit of the cap into the collar, and at least one detent groove sized and positioned appropriately for detenting engagement of the at least one detent bar fixed internally of the collar.

31. (Original, now cancelled) The device of Claim 30, wherein the cap has a vent hole to permit gradual escape of internal gasses through the port device even when the cap of the closure member is positioned to cover the aperture defined by the face plate.

32. (Original, now cancelled) The device of Claim 1, wherein the closure portion comprises an annular groove formed around the distal end of the internal side wall of the catheter and a cap, the cap having a shape and outside perimeter size which permit a liquid-tight, press fit of the cap into the distal end of the catheter, and an annular ridge formed around an outside wall of the cap sized and positioned appropriately for detenting engagement of the annular groove formed in the distal end of the catheter inside wall.

33. (Original, now cancelled) The device of Claim 32, wherein the cap has a vent hole to permit gradual escape of internal gasses through the port device even when the cap of the closure member is positioned to cover the aperture defined by the face plate.

34. (Original, now cancelled) The device of Claim 1, and further comprising a pad disposed between the proximally disposed side of the body portion of the device and the surface of the user's skin around the stoma, to thereby cushion the user's skin from contact with the device; the

pad being sized and shaped to fit snugly entirely around the perimeter of the stoma, to thereby further provide a moisture barrier to decrease the natural tendency of the tissue of the stoma to dry and become cracked or irritated.

35. (Original, now cancelled) The device of Claim 34, wherein the pad is formed of an open-cell foam material.

36. (Original, now cancelled) A self-retaining continent ostomy port device comprising:

(a) a generally planar face plate defining a selectively sealable aperture which is formed through and is alignable with the opening of a stoma formed in the body of a user of the device when the generally planar face plate of the device is disposed substantially parallel to the body wall of the user, over the site of the stoma, to thereby provide access to the inside of the stoma;

(b) a closure portion connected to the generally planar face plate adjacent to the aperture and adapted to permit selective and repeatable covering and uncovering of the aperture in the generally planar face plate; and

(c) a catheter portion having a first end and a second end, the first end of the catheter portion being connected to and extending from a side of the face plate which is disposed proximally when the port device is in normal use position, the catheter portion extending proximally and the second end of the catheter portion being disposed interior of the user's body, within the ostomy site when the port device is in normal use, the catheter portion having a continuous and generally cylindrical exterior side wall, and a continuous, generally cylindrical interior side wall defining a major lumen, the major lumen extending continuously from the aperture in the generally planar face plate to the second end of the catheter portion, the catheter portion being sized and shaped appropriately for non-surgical insertion through a stoma to a sufficient distance that the presence of the catheter portion within the stoma provides a physical

barrier which reduces prolapse without the use of extraneous, externally applied materials and devices or additional surgery; and

(d) retaining structure on the exterior side wall of the elongated catheter, the retaining structure being snugly fittable within the stoma, to thereby permit the continent ostomy port device to be indwelling for at least a period of days, without the need for extraneous fixation devices such as tape, belts, and adhesives or revisionary surgery, and further wherein the retaining structure is appropriately shaped and formed of material which permits the retaining structure to be bioresponsive, to thereby avoid tissue irritation and tissue damage due to compression of tissue by the retaining device.

37. (Original, now cancelled) A continent ostomy port device comprising:

- (a) a generally planar face plate defining a selectively sealable aperture which is formed through and is alignable with the opening of a stoma formed in the body of a user of the device when the generally planar face plate of the device is disposed substantially parallel to the body wall of the user, over the site of the stoma, to thereby provide access to the inside of the stoma;
- (b) a closure portion connected to the generally planar face plate adjacent to the aperture and adapted to permit selective and repeatable covering and uncovering of the aperture in the generally planar face plate;
- (c) a catheter portion having a first end and a second end, the first end of the catheter portion being connected to and extending from a side of the face plate which is disposed proximally when the port device is in normal use position, the catheter portion extending proximally and the second end of the catheter portion being disposed interior of the user's body, within the ostomy site when the port device is in normal use, the catheter portion having a

continuous and generally cylindrical exterior side wall, and a continuous, generally cylindrical interior side wall defining a major lumen, the major lumen extending continuously from the aperture in the generally planar face plate to the second end of the catheter portion, the catheter portion being sized and shaped appropriately for non-surgical insertion through a stoma to a sufficient distance that the presence of the catheter portion within the stoma provides a physical barrier which reduces prolapse without the use of extraneous, externally applied materials or additional surgery;

(d) a removable cartridge sized and shaped to fit snugly and slideably within the major lumen of the catheter portion of the device so as to be liquid-tight and to thereby prevent inadvertent escape of body waste material from the stoma through the device when the cartridge is in place, so that the user is not required to wear an ostomy bag, and to further thereby clean the interior side wall of the catheter portion as the cartridge is pressed into the major lumen of the catheter; and

(e) further comprising a selectively operable anti-reflux valve attached internally of the second end of the catheter portion, to thereby permit blockage of the major lumen by activation of the anti-reflux valve when it is desired to prevent escape of body waste through the port device, and to permit passage of fluid or solid material through the port device when the anti-reflux valve is deactivated.

38. (Original) A pad for use with a continent ostomy port, the pad comprising a body portion having an internal wall defining an aperture appropriately sized to place around a stoma, the body portion of the pad being sized and shaped for placement against a user's skin beneath a face plate of an ostomy port, the pad being formed of a soft, flexible material to thereby cushion and protect the skin from contact with the ostomy port face plate, wherein the body portion of the pad has a

stepped configuration on a distal surface thereof, the stepped configuration consisting of at least two distinct levels.

39. (Currently amended) The pad of claim 38, wherein the at least two distinct levels comprise a first level and a second level, the first level having a perimeter sized and shaped appropriately to readily fit within a perimeter of a face plate lip of a ~~COP~~ continent ostomy port, and the second level extending parallel to the first level and having a perimeter extending beyond the perimeter of the first level, beneath the lip of the plate, to thereby protect the user's skin from friction irritation.

40. (Original) The pad of claim 38, wherein the pad is formed of a material which is readily disposable.

41. (Original) The pad of claim 38, wherein the pad is formed of a material that is capable of being facilely cleaned and reused.

42. (Original) The pad of claim 38, wherein the distal surface of the pad is coated with a thin, liquid impermeable skin to thereby trap wicked moisture within the pad.

43. (Original) A pad for use with a continent ostomy port, the pad comprising a body portion having an internal wall defining an aperture appropriately sized to place around a stoma, the body portion of the pad being sized and shaped for placement against a user's skin beneath a face plate of an ostomy port, the pad being formed of a soft, flexible material to thereby cushion and protect the skin from contact with the ostomy port face plate, wherein a distal surface of the pad is coated with a thin, liquid impermeable skin to thereby trap wicked moisture within the pad.

44. (Original) The pad of claim 43, and further wherein the liquid impermeable skin is permeable to air, to thereby permit the pad area to breathe.

45. (Original) The pad of claim 43, wherein the pad is formed of a material which is readily disposable.

46. (Original) The pad of claim 43, wherein the pad is formed of material that is capable of being facilely cleaned and reused.

47. (Original) A pad for use with a continent ostomy port, the pad comprising a body portion defining an aperture appropriately sized to place around the catheter of a continent ostomy port, the body portion of the pad being sized and shaped for placement against a user's skin beneath a face plate of the ostomy port, the pad being formed of a soft, flexible material to thereby cushion and protect a user's skin from contact with the ostomy port face plate, wherein the pad body portion has a distal surface provided with a central indented region to thereby accommodate the distal portions of the continent ostomy port.

48. (Original) The pad of claim 47, wherein the central indented region of the distal surface of the pad body portion is generally cross-shaped.

49. (Original) The pad of claim 47, wherein the central indented region of the distal surface of the pad body portion has a substantially flat floor.

50. (Original) The pad of claim 47 wherein the central indented region of the distal surface of the pad body portion has a floor that defines the aperture for placement around a catheter of the continent ostomy port.

51. (Original) The pad of claim 47, wherein the distal surface of the pad is domed and the central indented region includes two opposed channels extending radially away from the center of the pad, to thereby permit access to a finger grip on a distal end of the continent ostomy port.

52. (Original) The pad of claim 47, wherein the central indented region includes two opposed cut-out areas extending radially away from the center of the pad, to thereby accommodate

structural features on a distal end of the continent ostomy port.

53. (Original) The pad of claim 47, wherein the pad includes a proximal surface having a depending ring disposed coaxially with the aperture in the pad and spacedly outwardly therefrom.

54. (Original) The pad of claim 53, and further comprising a channel formed between the depending ring and the perimeter of the pad.

55. (Original) The pad of claim 53, and further comprising a layer of adhesive on the proximal surface of the pad.

56. (Original) The pad of claim 47, wherein the pad is formed of a disposable material

57. (Original) The pad of claim 47, wherein the pad is formed of a material which can be cleaned and reused.

58. (Original) The pad of claim 47, wherein the body of the pad is generally oval.

59. (Original) The combination of a pad for use with a continent ostomy port and a shim, wherein the pad comprises a body portion defining an aperture appropriately sized to place around the catheter of a continent ostomy port, the body portion of the pad being sized and shaped for placement against a user's skin beneath a face plate of the ostomy port, the pad being formed of a soft, flexible material to thereby cushion and protect a user's skin from contact with the ostomy port face plate, wherein the pad body portion has a distal surface provided with a central indented region to thereby accommodate distal portions of the continent ostomy port, wherein the pad includes a proximal surface; and a shim having a through hole positioned coaxially with the aperture in the pad on the side of the proximal surface of the pad.

60. (Original) The combination of claim 59, wherein the pad has a depending ring on the proximal surface thereof, the depending ring being disposed coaxially with the aperture in the pad and spaced radially outwardly therefrom to thereby provide a channel between the depending

ring and the perimeter of the pad and the shim has an overall size and shape to permit the shim to fit snugly within the channel formed in the proximal surface of the pad.

61. (Original) The combination of claim 59, wherein the shim has an overall size and shape sufficient to permit the shim to hold the pad away from the user's skin.

62. (Original) The combination of claim 59, and further comprising a layer of adhesive on the proximal surface of the pad.

63. (Original) The combination of claim 59, wherein the perimeter of the pad is substantially oval.

64. (Original) The combination of claim 59, wherein the body of the pad is generally domed.

65. (Original) The combination of claim 59, wherein the distal surface of the pad is coated with a thin, liquid impermeable skin to thereby trap wicked moisture within the pad.

66. (Original) The combination of claim 59, and further comprising a layer of adhesive on at least one of the distal side and the proximal side of the shim.

67. (Currently amended) A method for protecting the skin of a user around a stoma of the user, comprising:

attaching a pad around a continent ostomy port, the pad having a body portion defining an aperture appropriately sized to place around a catheter of the continent ostomy port, and a distal surface provided with a central indented region to thereby accommodate distal portions of the continent ostomy port; and

positioning the pad beneath a face plate of the ostomy port against the user's skin for cushioning ~~an~~ and protecting the user's skin from contact with the ostomy face plate.

68. (Original) The method of claim 67, and further comprising the step of providing a shim having a through-hole and positioning the shim so that the through-hole aligns with the aperture

in the pad.

69. (Original) The method of claim 68 wherein the pad includes a proximal surface having a depending ring disposed coaxially with the aperture in the pad and spacedly outwardly therefrom and a channel formed between the depending ring and the perimeter of the pad, and the method further comprises disposing the shim snugly within the channel formed in the proximal surface of the pad between the depending ring and the perimeter of the pad.